K121511

Section 05
510(k) Summary

MAR 0 7 2013

510 (k) Summary of safety and effectiveness

APPLICANT

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Contract Manufacturer:	Multimedical s.r.l. Via Guido Rossa, 71 46019 Viadana (MN) Italy
CONTACT PERSON:	Enrico Bisson Studio ingegneria Enrico Bisson
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Date Summary Prepared: March 26, 2012

DEVICE IDENTIFICATION

A.	Trade name:	Maclin Power IV administration set
B.	Generic/ Common Name:	Intravascular Administration Set
C.	Classification name:	Intravascular Administration Set, 21 CFR 880.5440, Class II
D.	Product Code:	FPA

LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

CLAVE Connector, ICU Medical Inc., K970855
VITALCARE I.V. ADMINISTRATION SET, VITALCARE GROUP, INC, K050906
BURETTE-IN LINE, TUTA HEALTHCARE PTY, K023595
INTRAVASCULAR IV SET, IV SET WITH BURETTE, EXTENSION SET, LIFEMED OF CALIFORNIA, K001329

INTENDED USE

The Maclin Power intravascular administration is a single use, sterile device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.

DEVICE DESCRIPTION

The Maclin Power Intravascular Administration Sets are devices used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include one or more of the following: tubing, flow regulators, drip chamber, filters, backflow valves, fluid delivery tubing, clamps, connectors between parts of the set, needleless connectors, needleless Y sites, burettes, extension sets, Y tubing connector, protection caps and a hollow spike to connect the tubing to an IV bag or other infusion fluid container. Maclin Power will offer both standard sets and custom sets to meet customer specifications.

DISCUSSION OF NON CLINICAL TESTS

Bench test and biocompatibility tests were performed on the device and are included in this submission. The results of these tests supported the safety and effectiveness of the Maclin Power IV administration sets.

SUBSTANTIAL EQUIVALENCE

The indications for use of the Maclin Power IV administration set are substantially equivalent to the indications for use of the predicate devices. Materials used are similar and technological characteristics do not show any significant difference. In further support of a substantial equivalence determination, this submission provides a comparison chart of the submitted device and the predicate devices.

Based on the available information, we conclude that the Maclin Power IV administration set is substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act. Therefore, the applicant device is determined as safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2013

Maclin Power, Incorporated
C/O Mr. Enrico Bisson
President
Studio DI Ingegneria Enrico Bisson
Via Marzia, 9
Abano Terme, PD
Italy 35031

Re: K121511
Trade/Device Name: Maclin Power Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 25, 2013
Received: March 1, 2013

Dear Mr. Bisson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 04
Indications for Use Statement

INDICATIONS FOR USE

510(k) Number (if known): K121511

Device Name: Maclin Power Administration Set

Indications for Use:

The Maclin Power intravascular administration is a single use, sterile device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Richard C. Chapman 2013.03.07 10:43:06 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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